UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

MORPHOSYS AG, :

Plaintiff,

:

v. : Civil Action No. 99-1012 (JR)

:

CAMBRIDGE ANTIBODY TECHNOLOGY

LIMITED,

:

Defendant.

MEMORANDUM OPINION

In April 1999, MorphoSys sued for a declaratory
judgment that it does not infringe U.S. Patent Number 5,885,793
(the '793 patent), owned by Cambridge Antibody Limited (CAT) and
the Medical Research Council (of the United Kingdom), and that
the '793 patent is invalid under 35 U.S.C. §§ 102, 103, and 112.
CAT counterclaimed for infringement. After and in light of this
Court's claim construction memorandum of August 22, 2000,
MorphoSys moved for summary judgment as to CAT's counterclaim.
The claim construction was then amended by memorandum issued
October 11, 2000. The amendment effectively doomed the summary
judgment motion, which was denied. The infringement and
invalidity claims were tried in March 2001. The only issue the
jury was able to decide was that CAT's patent application is
entitled to a priority date of December 2, 1991. The jury was
not able to reach a unanimous verdict as to whether the MorphoSys

technology or the antibodies obtained using the MorphoSys technology infringed the '793 patent, or whether the '793 patent was invalid due to obviousness, anticipation, or lack of written description. Both parties moved after trial for judgment as a matter of law on a variety of grounds. MorphoSys also moved for reinstatement of the Court's original claim construction and conditionally renewed its motion for summary judgment as to CAT's infringement claim.

After careful consideration of the post-trial motions and of the record developed so far, it appears that MorphoSys should prevail on the issue of infringement, but because it is not clear that CAT has been "fully heard" on the issue, Fed. R. Civ. P. 50(a), the MorphoSys motions for summary judgment and for judgment as a matter of law on infringement will be in abeyance pending further proceedings or briefings. I have decided that CAT's motion for judgment as a matter of law must be granted as to MorphoSys's invalidity defenses of anticipation, written description, indefiniteness, and enablement. All other post-trial motions will be denied (except for CAT's motion to file surreply, which will be granted). The findings and conclusions that form the basis of these decisions are set forth below.

Findings of Fact

1. The '793 patent (PX 1) describes a method for obtaining

antibodies to specific human self antigens by the use of phage display libraries. The patent also covers the antibodies obtained using this method. The claims at issue in this case are the independent claim 1 and the dependent claims 2-6, 10-17, 31 and 37. Claim 1 of the '793 patent claims:

A method for obtaining a member of a specific binding pair, the specific binding pair member being an antibody or antibody fragment and having an antigen binding site comprising an antibody light chain variable region and an antibody heavy chain variable region, the antigen binding site having binding specificity for an antigen which is a human self antigen for which specific antibodies are not found in sera of humans unimmunized with said self antiqen the method comprising: (a) providing a library of filamentous bacteriophage, each filamentous bacteriophage displaying at its surface a specific binding pair member, and each filamentous bacteriophage containing nucleic acid with sequence derived from a human unimmunized with said self antigen and not having antibodies specific for said self antigen found in the sera and encoding a polypeptide chain which is a component part of the specific binding pair member displayed at the surface of that filamentous bacteriophage; and (b) selecting, by binding with said self antigen, one or more specific binding pair members with binding specificity for said self antigen.

2. The words "are not found" in the phrase "are not found in sera of humans" mean "are not present" in sera of any humans and not "were not found" or "have not yet been found." Cl. Constr. Mem. at 1 (Aug. 22, 2000). The words "derived from" in the phrase "nucleic acid with sequence derived from a human" mean "acquired

¹ CAT moves for judgment as a matter of law on the validity of the unasserted claims: 7-9, 18-30, 32-36, and 38-41. Because it does not appear there was ever a case or controversy as to those claims, the motion will be denied as moot.

or obtained, actually or theoretically, directly from, or by modification of," but not "by reference to," human material.

Order on Recons. at 4 (Oct. 11, 2000).

- 3. When CAT filed its patent application, it was working with "natural" libraries, using lymphocytes taken physically from the blood of one or two individuals. (Trial Tr. 251-52, 640 (videotape of Winter dep. 173).) Examples 1-4 in the '793 patent (Plf.'s Ex. 1: col. 22, l.1 col. 30, l.7) are experiments using the "natural" library.
- 4. CAT also developed what it called a "synthetic" library, using a human donor, cloning capital V-gene segments, and amplifying them by the use of synthetic primers. (Trial Tr. 640 (videotape of Winter dep. 181).) Examples 5-7 in the '793 patent (Plf.'s Ex. 1: col. 80, 1.18 col. 36, 1.45) are experiments using the "synthetic" library.
- 5. Although there is a substantial dispute about whether, and to what extent, the '793 specification, drawings, and descriptions enable a "fully synthetic" library to one of ordinary skill in the art (Compare MorphoSys's Proposed Findings of Fact (Enablement) ¶¶ 16, 17, 21, with CAT's Resp. Proposed Findings of Fact (Enablement), Resp. to ¶¶ 16, 17, 18) CAT does not contend

that the '793 specification, drawings, and descriptions enable a phage display library derived by "theoretical analysis" (see CAT Combined Opp. Fed. R. Civ. P. 50(b) & 52, at 24-25).²

- 6. The MorphoSys HuCAL library starts, not with human blood, but with data -- amino acid sequences reported on Internet-accessible databases. The sequences are grouped and analyzed "in silico" (in the computer) and then synthesized on the DNA synthesizer. (Trial Tr. 737-51; Knappik et al., "Fully Synthetic Human Combinatorial Antibody Libraries (HuCAL) Based on Modular Consensus Frameworks and CDRs Randomized with Trinucleotides," J. Mol. Biol (2000) 296, 57-86 (Ex. A to MorphoSys Mot. for Partial Summ. J.).)
- 7. The accused antibodies or antibody fragments specific to human self antigens KGF-R, ICAM-1, PD-1, FLICE, TrkA, alpha e beta 7 integrin, and sprouty were obtained from MorphoSys HuCAL libraries and shipped to customers of MorphoSys. (Stipulation Establishing Facts for Trial ¶¶ 5, 7, 10, 13, 15, 17, 19.) The antibody fragments against human self antigens FGF-18 and CHK-1

² MorphoSys asserts (without citation to the record) that, to make nucleic acid with sequence "created using a theoretical analysis of published sequences," a skilled artisan would need full length human antibody sequences from which to make the analysis, or directions to published sequences or databases of published sequences; a theory for analyzing published sequences; and a computer program, mathematical algorithm, or other means for performing the analysis. Enablement Brief at 13-14.

were obtained by a MorphoSys customer from a MorphoSys HuCAL library. (Id. ¶ 30.)

8. Applications for British patents filed by CAT on December 2, 1991, include a written description of the entire scope of the invention claimed in the '793 patent and provide sufficient information to enable a person of ordinary skill in the art to make and use that claimed invention. (Jury verdict.)

Discussion

Judgment as a matter of law is appropriate when "a party has been fully heard on an issue and there is no legally sufficient evidentiary basis for a reasonable jury to find for that party on that issue." Fed. R. Civ. P. 50 (a)(1). A court presented with a motion renewed after trial under Rule 50(b) must view the evidence presented to the jury in the light most favorable to the non-moving party, giving the non-moving party the benefit of all reasonable inferences, but will grant judgment in favor of the party bearing the burden of proof "only where (1) the movant 'has established [its] case by evidence that the jury would not be at liberty to disbelieve' and (2) 'the only reasonable conclusion is in [the movant's] favor.'" Nobelpharma

AB v. Implant Innovations, 141 F.3d 1059, 1065 (Fed. Cir. 1998).

1. Infringement

There are two infringement issues. The first is what the parties have called the "donor limitation" issue, which is whether or not antibodies specific to the nine accused antigens are found in the sera of unimmunized humans. This was the only question submitted to the jury in connection with CAT's infringement claims, and the jury was unable to decide it. The other issue relates to the so-called "antibody limitation" and raises the question of whether the MorphoSys HuCAL libraries are "derived from a human unimmunized with said self antigen." That question essentially became dormant after I denied MorphoSys's motion for reconsideration of the amended claim construction. The denial, however, was "without prejudice to either party's revisiting the question of claim construction as the litigation proceeds." The post-trial motions of the parties have revived the antibody limitation issue.

a. The "donor" or "are not found" limitation

On its claim of infringement as to the donor limitation, CAT had the burden of proving by a preponderance of the evidence that each of the nine accused antigens is one "for which specific antibodies are not found in the sera of human unimmunized with said self antigens." Both sides have moved for judgment as a matter of law on this claim.

CAT relies upon Dr. Cohen's testimony that specific

antibodies are rarely found due to tolerance (Trial Tr. 275-77), and upon Dr. Jackson's testimony that his literature search turned up no evidence of the accused antigens having been found (Trial Tr. 364-74). That testimony would have been sufficient to support a verdict in CAT's favor on this issue had the jury reached such a verdict. On the other hand, Dr. Golub's testimony that, more likely than not, antibodies to the nine self antigens are indeed found in the sera of unimmunized humans (Trial Tr. 276), considered with Dr. Jackson's admission that he could have performed further testing to determine that the accused antigens "were not found" (Trial Tr. 499), would have permitted a jury to find in favor of MorphoSys. Neither side has established that "the only reasonable conclusion is in its favor" on the donor limitation infringement claim. Nobelpharma, 141 F.3d at 1065.

b. The "antibody" or "derived from" limitation

The "derived from" language of Claim 1's limitation to nucleic acid "with sequences derived from a human" was first construed to mean "produced from or derived by physical means" and "not broad enough to cover sequence that is isolated theoretically or only by reference to a human being." Cl. Constr. Mem. at 3 (Aug. 22, 2000). Upon reconsideration, the language was construed to mean "acquired or obtained, actually or theoretically, directly from, or by modification of." Now that I have heard testimony explaining the nature of theoretical

analysis of published sequences, such as that used in the HuCAL library (Trial Tr. 737-51), it seems clear to me that no reasonable jury could find that the HuCAL library, whose starting point is theoretical analysis of data, is "derived from a human" -- and certainly not "from a human unimmunized with the said self antigen and not having antibodies specific for said self antigen found in the sera." The derivation of nucleic acid from computer analysis of sequences found in published databases would seem to amount at most to derivation "by reference to" a human - an additional meaning of the phrase "derived from" that was proposed by CAT but expressly excluded from this Court's construction of the claim.

It seems clear, further, that a ruling to this effect would neither conflict with nor require a further amendment of the Court's construction of the donor limitation. MorphoSys's HuCAL library and CAT's "semi-synthetic" library both may be said to have "theoretical" components, but they appear to be derived in completely different ways. Because the antibody limitation issue was not presented to the jury, however, and because MorphoSys's post-trial renewal of its summary judgment motion relies on a construction of the antibody limitation that is inoperative, the parties' cross-motions as to infringement will

³ CAT's "semi-synthetic" library contains very small percentages of random nucleic acid connector sequence that makes the completed sequences in some sense "theoretical." (Trial Tr. 797.)

be in abeyance pending further briefing or other appropriate proceedings.

2. Invalidity Defense Tried to the Jury

MorphoSys and CAT have both moved for judgment as a matter of law on the three invalidity defenses that were tried to the jury: obviousness, anticipation, and written description.

a. Obviousness

Obviousness is a conclusion of law, but it rests on factual findings such as the scope and content of prior art, the differences between the prior art and claimed invention, and the level of skill in the art. Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966). MorphoSys had the burden of showing by clear and convincing evidence that "differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a). MorphoSys attempted to sustain that burden by pointing to Winter, Clackson and Larrick, arguing that they taught that human self-antibodies would be found in phage display libraries and that it would have been "stupid not to try." (Trial Tr. 1290:19.) CAT's response was to show that the Winter and Clackson references were considered and dismissed by the

⁴ Dillon is prior art only if MorphoSys establishes that CAT is not entitled to the December 2, 1991 effective filing date.

Patent Office, and to argue that the bias in the art was so strong that one of ordinary skill would have thought there was no probability of success.

The jury could not decide whether the prior art would have suggested to one of ordinary skill in the art that antibodies specific to human self antigens could be obtained from phage display libraries, and whether the bias against a successful effort was strong enough that a person of ordinary skill in the art would not think to try. (Compare Trial Tr. at 801, 817, 832-44 (Dr. Barbas saying it would be obvious) with Trial Tr. 1057 (disputing Clackson), 275-76 (theory of tolerance).) Neither side of the issue is so clear as to be amenable to judgment as a matter of law.

b. Anticipation and Written Description

A patent claim is invalid for anticipation if all of its limitations have been disclosed in a single prior art reference. "[T]hat which would literally infringe if later in time anticipates if earlier than the date of invention." Lewmar Marine, Inc. v. Barient, Inc., 827 F.2d 744, 747 (Fed. Cir. 1987). It is MorphoSys's position that the Dillon '750 patent, with a § 102(e) priority date of February 28, 1992, anticipated the '793 patent. CAT, however, claims a priority date earlier than Dillon's. If that claim is correct, the anticipation defense fails as a matter of law. The question is whether the

disclosures of two British applications filed by CAT on December 2, 1991, met the written description requirement, entitling CAT to priority as of the date they were filed.

The jury found for CAT on this issue, having been instructed that they could do so only if they found that the British applications met two requirements: "(1) that it include[d] a written description of the entire scope of the invention claimed in the U.S. patent, and (2) that it provide[d] sufficient information to enable a person of ordinary skill in the art to make and use that claimed invention." The jury's finding was supported by substantial evidence, and particularly by the testimony of Dr. Jackson, who walked the jury through the British patent applications, explaining where scientists in the field would find a description of a fully synthetic library. (Trial Tr. 957-71, 1002-34.) That verdict will not be disturbed and is dispositive of the anticipation defense.

MorphoSys's correlative defense of invalidity for lack of written description fails for the same reason. Its burden was to show by clear and convincing evidence that the patent applicant failed to convey with reasonable clarity to those skilled in the art that the inventors invented what is claimed, even though a written description need not use the exact words of the claims in question and may even be found in the inherent disclosure of the application. See Ralston Purina Co. v. Far-Mar-Co., Inc., 772 F.2d 1570, 1575 (Fed. Cir. 1985). MorphoSys

argues that the '793 specification fails to meet the written description requirement because it "adds little to the original U.K. applications" (MorphoSys Br. Jury Invalidity Issues at 22), but the meaning of the jury's verdict is that the British applications were enough. MorphoSys has not proved otherwise.

3. Indefiniteness

MorphoSys moves for judgment as a matter of law on indefiniteness, an invalidity defense that was not tried to the jury. A patent is invalid for indefiniteness if it does not "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112. "'[T]he limits of a patent must be known for the protection of the patentee, the encouragement of the inventive genius of others and the assurance that the subject of the patent will be dedicated ultimately to the public.' Otherwise, a 'zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims would discourage invention only a little less than unequivocal foreclosure of the field.'" Markman v. Westview, 517 U.S. 370, 390 (1996) (citing United Carbon Co. v. Binney & Smith Co., 317 U.S. 228, 236 (1942)).

MorphoSys argues that the '793 patent's coverage of antibodies to human self antigens for which "specific antibodies are not found in the sera of humans" creates just such a zone of

uncertainty. MorphoSys asserts that a scientist who locates an antibody from a phage display library has no way of determining with assurance whether or not that antibody is within the scope of the '793 patent because there is no practical way of determining whether or not the antibody is found in the sera of immunized humans. Because MorphoSys has failed to sustain its burden of proving indefiniteness, judgment as a matter of law on this issue will be entered in favor of CAT.

CAT's submission begins with the proposition that antibodies against human self antigens are "not generally found" in the sera of unimmunized humans (Trial Tr. 300:16 - 301:5) so that anyone choosing to obtain one is at risk of infringing the '793 patent. The risk is manageable, however. One may undertake a literature search and proceed safely if the search reveals that specific antibodies to the human self antigen of interest have been found. "[I]f the skilled person does not consider the literature searches to be sufficient, then testing can be performed." (CAT Combined Opp. Mem. at 44.) "[A]ny test that . . . finds in human sera specific antibodies to the human self antigen of interest will exclude antibodies against that antigen from the scope of the claims of the patent." (CAT Combined Opp. Mem. at 45.)

MorphoSys objects that what is -- or is not -- "found in sera of unimmunized humans" is an ever-changing proposition.

Indeed, five of the human self antigens originally claimed by CAT

had to be withdrawn when, notwithstanding Dr. Cohen's "not generally found" testimony, further research showed that antibodies specific to those antigens had been found in unimmunized humans. (Stipulation of Facts for Trial ¶ 34.)

CAT's expert Dr. Jackson acknowledged that new antigens are discovered every week, and that their discovery is not reflected immediately in the literature. (Trial Tr. 514:1-16.) Dr.

Jackson's testimony effectively conceded, for that matter, that a literature search does not provide certainty, and that a competitor cannot be assured of noninfringement without performing tests. (Trial Tr. 546:14 - 549:21.) And, as for the tests, CAT's expert Dr. Cohen conceded that whether or not an antibody tests "specific" to a human self antigen will depend on the parameters set by the scientist doing the testing. (Trial Tr. 322:19-25.)

It is settled, however, that experimentation may be needed to determine the limits of a claim, that the need for such experimentation does not itself render a claim indefinite, and that some subjectivity in a test is allowable if it will not confuse one with ordinary skill in the art. See Seattle Box Co.

v. Industrial Crating & Packing, Inc., 731 F.2d 818, 826 (Fed.

⁵ Either way, the content of an article may not be revealed by searching the titles or abstracts. And even if "the literature" does report the presence of a self antigen in unimmunized humans, CAT reserves the right to disagree with another scientist's findings. (Trial Tr. 546-49.)

Cir. 1984); W.L. Gore & Assoc., Inc. v. Garlock, Inc., 721 F.2d 1540, 1556 (Fed. Cir. 1983). The indefiniteness question comes down to whether the ELISA assay upon which CAT relies enables even one skilled in the art to determine whether an antibody is specific to some human self antigen, and whether one skilled in the art must engage in "undue experimentation" to determine whether a particular antibody infringes the '793 patent. See In re Angstadt, 537 F.2d 498, 503-04 (C.C.P.A. 1976).

MorphoSys has not sustained its burden of proving that the ELISA assay is too uncertain. The test is specified (col. 25, 11.9-19; col. 20, 1.60 - col. 21, 1.16), reference is made to a source of further details for the specificity test (col. 5, 11.54-55), and there is credible expert testimony of record that the results of an ELISA assay would be relied upon by one skilled in the art. CAT also has the better of the argument on the time required to conduct an ELISA assay after the initial setup. (See CAT Combined Opp. Mem. at 45.)

In strictly logical terms, of course, nobody can be absolutely certain that a particular antibody is "not found in the sera of unimmunized humans" unless everyone in the world is tested. But that is not the kind of uncertainty addressed by Justice Jackson's "zone of uncertainty" dictum in <u>United Carbon</u>

<u>Co. v. Binney & Smith Co.</u>, 317 U.S. 228, 236 (1942), 6 and, in any

⁶ The <u>United Carbon</u> decision found "bad for indefiniteness" certain claims for a process of converting carbon black to

case, neither party pursues this version of the indefiniteness argument in its briefs, probably because patent law is less cosmic and more practical: A test or other process for determining whether a patent has been infringed need be only as "precise as the subject matter permits." Hybritech Inc., v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1385 (Fed. Cir. 1986). It was MorphoSys's burden to establish that the literature search cum ELISA assay approach was not that precise. MorphoSys did not sustain its burden.

4. Enablement

MorphoSys's fifth invalidity defense, on which it also moves for judgment as a matter of law, is lack of enablement. A patent specification must "contain a written description of the invention, and the manner and process of making and using [it], in such full, clear, concise, and exact terms as to enable any person skilled in the art to which that invention pertains, or with which it is most nearly connected, to make and use that invention.... [T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full

aggregated form because the claims described the invention almost entirely in terms of its function. The Court's discussion of a "zone of uncertainty" added nothing of substance to that finding. The phrase was repeated by Justice Souter in Markman v. Westview Instruments, Inc., 517 U.S. 370, 390 (1996), not to illuminate a holding of indefiniteness, but in aid of the Court's holding that courts and not juries should construe patent claims.

scope of the claimed invention without 'undue experimentation.'"

In re Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993). "The scope of enablement, in turn, is that which is disclosed in the specification plus the scope of what would be known to one of ordinary skill in the art without undue experimentation."

National Recovery Techs., Inc. v. Magnetic Separation Systems,

Inc., 166 F.3d 1190, 1196 (Fed. Cir. 1999). The question of whether or not a disclosure is enabling is one of law, the answer to which is based upon several underlying factual inquiries. See In re Wands, 858 F.2d 731, 735, 736-37 (Fed. Cir. 1988).

MorphoSys's position is that '793 patent enables only natural libraries, nothing theoretical. MorphoSys concedes that "the '793 patent need not enable HuCAL" to be valid, but argues that the '793 patent "must enable some type of library in which nucleic acid has sequence that is theoretically derived."

(MorphoSys Reply Br. Enablement at 5.) Although CAT's library does not begin with theoretical analysis of published sequences as does the HuCAL, CAT's description of a semi-synthetic library does enable a phage display library that is "theoretical" in the sense that 3-5% of the total is made up of random nucleic acid

⁷ MorphoSys makes this argument with respect to the British application as well. The jury's verdict, while not dispositive of the enablement question, is supported by substantial evidence in the record. This Court will adopt the jury's findings and conclude from them that MorphoSys has not proved by clear and convincing evidence that the British applications do not enable the claimed invention.

connector sequences. (Trial Tr. 797; Col. 9, 1.66 - col. 10, 1.20). This conclusion is consistent with the jury's verdict that the U.K. patent applications adequately enabled one of ordinary skill in the art to make and use the claimed invention.

MorphoSys's further enablement arguments deal with the nature of the testing that is required to determine the specificity of antibodies, a subject that is also raised by the indefiniteness defense, discussed supra. The '793 patent clearly references ELISA testing and suggests to one of ordinary skill that such testing would be the way to determine the specificity of antibodies. (Col. 25, 11.9-19; col. 20, 1.60 - col. 21, 1.16; col. 5, 11.54-55). ELISA testing is as precise as the art permits. The degree of experimentation required is not undue: setting up the test might take several months, but the test itself is a relatively quick procedure (Trial Tr. 573-74), that was clearly described in the '793 specifications, (Col. 25, 11.9-19; col. 21, 1.16; col 5, 11.54-55), and which a scientist of ordinary skill would be able to perform.8

⁸ MorphoSys's argument that the British patent applications do not enable the invention because they do not specify the ELISA assay is rejected and would be rejected even if it were not inconsistent with the jury's verdict as to priority. There was no requirement to specify ELISA testing unless such testing was beyond what "is disclosed in the specification plus the scope of what would be known to one of ordinary skill in the art."

National Recovery Techs., 166 F.3d at 1196. MorphoSys did not prove by clear and convincing evidence that such testing would not be known to one of ordinary skill given the references in the British patent applications. (Trial Tr. 963-67.)

	JAMES ROBERTSON
	United States District Judge
Dated:	

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UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

MORPHOSYS AG, :

Plaintiff,

.

v. : Civil Action No. 99-1012 (JR)

CAMBRIDGE ANTIBODY TECHNOLOGY

LIMITED,

:

Defendant.

ORDER

For the reasons set forth in the accompanying memorandum opinion, it is this _____ day of August, 2001,

ORDERED that the motions for judgment as a matter of law of MorphoSys AG and Cambridge Antibody Technology, Ltd. [#195, #198, #211, #215] are **granted in part** and **denied in part**, as follows: Both parties' motions are denied as to the invalidity defense of obviousness. CAT's motion is granted and MorphoSys's denied as to the invalidity defenses of anticipation, written description, indefiniteness, and enablement. CAT's motion as to the unasserted claims is denied as moot. And it is

FURTHER ORDERED that the motion of Cambridge Antibody Technology, Ltd. for leave to file surreply [#246-1] is **granted**.

JAMES ROBERTSON United States District Judge

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